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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,840	06/20/2000	Dewen Qiu	19603/3340 (CRF D-2018B)	6516

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EXAMINER
KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	16

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/597,840	Applicant(s) QIU ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-51* is/are pending in the application.

4a) Of the above claim(s) *40,42-45 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,39,41 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10/1/02 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. As requested in Paper No. 11, filed 1 October 2002, claims 38-39 and 41 have been amended. Claims 40, 42-45 and 51 remain withdrawn from consideration as being drawn to nonelected inventions. Claims 38-39, 41 and 46-50 are examined to the extent they read on transformation with a nucleic acid encoding a hypersensitive response elicitor from *Erwinia amylovora*. Non-elected claims and elicitors should be cancelled in response to this Office action.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The draftsman has approved the drawings as submitted.

Response to Amendment

4. The rejection of claims 38-39, 41 and 46-50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is WITHDRAWN in light of amendments to the claims.

Claim Rejections - 35 USC § 112

5. Claims 38-39, 41 and 46-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the

reasons of record as set forth in the Office action mailed 27 March 2002. Applicant's arguments filed 1 October 2002 have been fully considered but they are not persuasive.

Applicant urges that patent applications for the *hrpW*, *dspE* and *dspF* genes were filled long after the filing date of the instant application, showing that hypersensitive response elicitors and the genes encoding them are an art-recognized class of compounds. Applicant describes the hypersensitive response, citing Gopalan et al, and urges that genes controlling hypersensitive response elicitation and pathogenesis are recognized in the art to be present in a limited class of Gram-negative pathogens, citing Bonas, 1994I, Bogdanove et al, and Gopalan et al. Applicant urges that hypersensitive response elicitors share a number of characteristics, including being glycine rich, heat stable, hydrophilic, capable of inducing HR, susceptible to proteolysis and lacking cysteine, citing Bonas et al, 1994II, and Preston et al. Applicant urges that hypersensitive response elicitors from bacteria within a given genus are homologous to one another, citing Willis et al, Ahmad et al, Gopalan et al, and Arlat et al, and that genes encoding hypersensitive response elicitors from different genera are so similar that they can be used as probes to isolate other such genes, citing Van Gijsegem et al, Bogdanove et al, Bauer et al 1995, Bauer et al, 1994, Cui et al, Ahmad et al, 1996I, Ahmad et al 1996II, and Laby et al (response pg 5-9).

This is not found persuasive because the specification does not describe the sequence of any nucleic acids encoding hypersensitive response proteins from *E. amylovora* other than SEQ ID NO:4. That the *hrpW*, *dspE* and *dspF* genes could be identified after the filing of the instant application as encoding hypersensitive response proteins is not relevant; the instant specification itself does not describe the sequence of the nucleic acid encoding 3 of the 4 known hypersensitive response proteins from *E. amylovora*. The specification also does not describe

the features that distinguish *E. amylovora* hypersensitive response elicitor genes from other hypersensitive response elicitor genes.

See *In re Shokal,* 113 USPQ 283, (CCPA 1957) at pg 285

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. ...
> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

6. Claims 38-39, 41 and 46-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes the HrpN protein from *E. amylovora*, does not reasonably provide enablement for a method of enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes any hypersensitive response elicitor protein from *E. amylovora*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is modified from the 35 U.S.C. 112, first paragraph, rejection set forth in the Office action mailed 27 March 2002. Applicant's arguments and the Declaration of Zhong-Min Wei, both filed 1 October 2002, have been fully considered but they are not persuasive.

Applicant urges that the specification outlines the basic steps of plant transformation, which are well-known in the art. The declaration of Wei shows that *Arabidopsis* and cotton plants transformed with a nucleic acid encoding HrpN from *E. amylovora* grew at a greater rate

than wild-type plants and that topical application of hypersensitive response proteins from other bacteria genera enhanced the growth of tomato (response pg 9-10 and the Declaration).

This is not found persuasive. The instant specification fails to provide guidance for transformation of a plant with *E. amylovora* hypersensitive response elicitor genes other than SEQ ID NO:4 because it fails to teach *E. amylovora* hypersensitive response elicitor genes other than SEQ ID NO:4.

The Declaration provides evidence that the specification is enabled for a method of enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes the HrpN protein from *E. amylovora*.

Double Patenting

7. Claims 38-39, 41 and 49-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-16 of U.S. Patent No. 6,174,717. The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 March 2002. Applicant's arguments filed 1 October 2002 have been fully considered but they are not persuasive.

Applicant urges that the claims of the issued patent relate to transgenic plants generally and have nothing to do with a method of growth enhancement in plants (response pg 11).

This is not found persuasive because growing the plant of the issued patent or seed thereof, which plant is transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*, would inherently result in practicing the method of the instant application, which method entails enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from

E. amylovora. Simply generating the plants and seeds claimed in the issued patent would result in practicing the method of the issued patent because generating would involve growing the plants. The transformed plants would have enhanced growth at least in the presence of pathogens.

8. Claims 38-39, 41 and 46-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of U.S. Patent No. 6,228,644. The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 March 2002. Applicant's arguments filed 1 October 2002 have been fully considered but they are not persuasive.

Applicant urges that the claims of the issued patent relate to transgenic plants generally and have nothing to do with a method of growth enhancement in plants (response pg 11).

This is not found persuasive because growing the plant of the issued patent or seed thereof, which plant is transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*, would inherently result in practicing the method of the instant application, which method entails enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*. Simply generating the plants and seeds claimed in the issued patent would result in practicing the method of the issued patent because generating would involve growing the plants. The transformed plants would have enhanced growth at least in the presence of pathogens. The plants of both the issued patent and the instant application include the same plant species.

9. Claims 38-39, 41 and 45-50 are free of the prior art, given the failure of the prior art to teach or suggest a method of enhancing growth in plants by transforming a plant or seed with a nucleic acid that encodes a hypersensitive response protein from *E. amylovora*.

10. No claim is allowed.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
December 16, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638